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Posey Company

5635 Peck Road • Arcadia, California 91006-0020 U.S.A.

Customer Service
Toll Free: (800) 44-POSEY
Tel: (818) 443-3143
Fax: (818) 443-5014

SAFETY AND EFFECTIVENESS SUMMARY

JT Posey Company
5635 Peck Road
Arcadia, CA 91006
Michael Keefe
General Manager
August 30, 1996

Revised: November 18, 1996

Phone # (818) 443-3143
FAX # (818) 443-5014

Reference Number: K963436

Trade Name: Protective Restraints
Common Name: Restraint Accessories
Classification Name: Protective Restraints

The devices included in this 510(k) submission facilitate attachment of protective restraint devices to vehicles. These devices provide anchor points for tying quick release knots and/or adapts protective restraints with quick release buckles. The products are then secured to the bed, geriatric chair, or wheelchair via the accessory device. The accessory devices attach directly to the vehicle.

These products are facilitate attachment of devices that are intended to hinder egress or aid in positioning of a patient in a wheelchair, hospital bed, geriatric chair, or gurney.

The devices used for comparative purposes are identical to the restraint accessories as described in this submission and produced or sold by the J.T. Posey Co. This premarket submission is submitted in response to the agency's final rule published on March 4, 1996 in the Federal Register 21 CFR 880 and 21 CFR 890 Medical Devices, Protective Restraints - Revocation of Exemptions from 510(k) Pre-market Notification Procedures and Current Good Manufacturing Practice Regulation. The June 13, 1996 Meeting Minutes, HIMA Body Holder Task Force and FDA CDRH established the rationale for which devices would be used for comparison:

"Predicate device

FDA indicated that it would be appropriate for manufacturers to reference their current products as legally marketed devices for comparison purposes in their submissions. It would also be appropriate to reference any approved 510(k)s that manufacturers have submitted for their products."

The restraint accessories are currently exempt from 510(k) Premarket Notification Procedures and Good Manufacturing Practice Regulations and are **legally marketed** by JT Posey Co. as of the date of this submission, August 30, 1996. The limb holders have been manufactured and in commercial distribution for up to 20 years.